SKIRGESA

Certificate ofDesignation

This is to certify that, we SKIRGESA Ltd. act as the EU Authorized Representative for the below mentioned manufacturer and agree to perform all duties and responsibilities as the EC REP according to the medical device regulation (EU) MDR 2017/745.

The manufacturer has provided us with the appropriate documentations and a declaration of conformity for the product: Alginate Impression Material (list ofproducts see annex)

Company Name:	GULIXDENT INC.
Company Address:	4/F, Building 4, Plot D-04-2a, Information Industrial Park, Qixing District, Guilin, P.R.China
Applicable EU Regulation & Annex:	Complying with European Medical Device Regulation (EU) MDR 2017/745 article 52 requirements, including EU declaration of conformity (according to the annex IV) including all general safety & performance requirements.

The certificate remains valid nroviding the manufacturer maintains their documentation in comnliancewith the FU legislation and until expiration of the FU ren agreementl

European Authorized Representative (EC REP)
SKIRGESA Ltd. [SRN: LT-IM-000004084]
Energetiku st. 8, Kaunas 52461, Lithuania

CE

The product liabiity rests with the manufacturer in accordance with applicable directive and standard, after fulfiling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to mentioned products

Signature: Direktorius

Date:

Declaration of Conformity

according to the Medical Devices Regulation2017/745/ EU

This is to state that Technical Documentation (HJY-CE-A/9-2021) for product(s)

Manufacture: GULIXDENT INC.

4/F, Building 4, Plot D-04-2a, Information Industrial Park, Qixing District, Guilin, P.R.China

Authorised Representative: (To be provided when necessary.)

Medical Device Product Name : Alginate Impression Material

MDR-Classification : Class Ⅰ, Rule 5

Product standard: ISO21563:2013 Dentistry — Hydrocolloid impression materials

UDI:697068808HYGESM

Specified name:

Gulixdent Alginate Impression Material ;
Chromatic Alginate Impression Material;
GulixChroma Alginate ImpressionMaterial;
Gulix Alginate Impression Material ;
GulixPLUS Alginate Impression Material

The undersigned hereby declares that the medical device as specified above conforms to the essential requirements listed in the Annex I of the European Medical Device Regulation 2017/745/EU (MDR).

This declaration of conformity is based on the European Medical Device Regulation 2017/745/EU, Annex IV .

General Manager

Mr. Huang Yang Ming

February 6, 2025

CE

(name and signature orequivalent marking of authorized person)